

Exhibit N



FDA Contact Report

DATE: February 8, 2005

FDA PERSONNEL: Jenny Liu, Nurse Consultant
Division of Postmarket Surveillance
Office of Surveillance and Biometrics
jenny.liu@fda.hhs.gov
301-594-3948

BARD PERSONNEL: Shari L. Allen, BPV

SUBJECT: Recovery Filter - Update

Jenny Liu at the Food and Drug Administration (FDA) contacted me on February 8, 2005. The purpose of the communication was to request additional information on the Recovery Filter System.

Ms. Liu indicated that she is responsible for reviewing Medical Device Reports (MDR) at the FDA, and she is contacting all retrievable filter manufacturers to obtain additional information. She indicated that she has observed an increased trend in MDR reportable events for all retrievable filters, specifically in bariatric patients. She said she believes that this is because the retrievable indication provides a treatment option for new patient populations, including bariatric patients. I asked her if she has any specific concerns with retrievable filters. She said not at this time, but she is very interested in gaining a better understanding of retrievable filters and the new patients populations that are receiving retrievable filters, including bariatric patients. I asked for clarification on the nature of the request and to whom the request is being sent. She indicated that the request is related to how the various manufactures distinguish between the permanent indication and the retrievable indication. She also confirmed that the Recovery Filter System is not being singled out and that she is sending the request to all three retrievable filter manufacturers.

I asked Ms. Liu if she had received a copy of the proposed customer letter from Lisa Kennell in the FDA Office of Device Evaluation (ODE). She said she has not received it, but she will follow up with Ms. Kennell. I told her that the purpose of the letter is to inform our customers of BPV's internal analysis of reported adverse events related to the Recovery Filter System, specifically concerning the bariatric patient population. She said that she believes it is a very good idea to send this type of letter and appreciates BPV being so proactive. I also told her that we plan to convene an expert panel of bariatric surgeons on Saturday, February 12, 2005, and we would really like to receive her input prior to this date. She said that she will be out of the office on Wednesday and Thursday, but she will return Friday. She said that she will try very hard to get back to me by Friday evening.

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I closed the discussion by telling Ms. Liu that I will watch out for her fax identifying questions concerning the Recovery Filter System, and I will look forward to receiving her comments on the proposed letter on Friday.

cc: Brian Barry
Rob Carr
David Ciavarella
Len DeCant
Joe DeJohn
Chris Ganser
Janet Hudnall
John McDermott
Kevin Shifrin
Doug Uelmen

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